

REMARKS

Claims 65-75 are currently pending. Claims 65 and 71 have been amended to correct typographical errors. Support for the amendments may be found in the specification, for example, at paragraphs [0018], [0024], [0028], [0049], [0051], [0054] and [0056] of the pre-grant publication. These amendments do not constitute new matter.

Claims 65 and 71 are objected to.

Claims 65-75 stand rejected under 35 U.S.C. § 112, ¶ 1, for lack of adequate written description.

Claim Objection

The Examiner has objected to claims 65 and 71 because “CH1b” should presumably be “anti-CD1b” in the last line of the claims. In response, claims 65 and 71 have been amended as suggested by the Examiner. Accordingly, Applicants respectfully request withdrawal of this objection.

Claims 65-75 are adequately described

The Examiner has raised a new matter rejection of claims 65-75 under 35 U.S.C. § 112, ¶ 1, “as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the art in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.” In particular, the Examiner contends that more of the limitations introduced by the previously presented amendments to steps (c) and (d) of claims 65 and 71 are only found in Example 6, which “discloses only a method of generating human dendritic Langerhans cells from human

peripheral blood monocytes” and “is limited to a method employing only autologous platelets in RPMI-1640 medium with or without 2% fetal calf serum,” and suggests that all limitations in Example 6 be included in the claims. Applicants respectfully traverse this rejection.

A. Applicants have properly identified support for the previously presented claim amendments

The instant application discloses an *in vitro* method for producing mammalian dendritic Langerhans type cells, comprising (a) culturing peripheral blood monocytes or bone marrow cells from a mammalian species with platelets from the same species or phylogenetically close species; (b) incubating the culture to generate dendritic Langerhans type cells; (c) performing a morphological analysis of the generated dendritic Langerhans type cells; and (d) performing a flow cytometric analysis of the generated dendritic Langerhans type cells (*e.g.*, paragraphs [0006]-[0029]; Original Claims 7-9).

To illustrate each step of the invention, the specification provides six (6) examples. For instance, Examples 5 and 6 relate to the morphological analysis step and the flow cytometric analysis step of the invention, respectively. In addition to these examples, the specification discloses two specific experiments according to the invention. In the first experiment, dendritic Langerhans type cells were generated *in vitro* from human peripheral monocytes induced by human platelets (paragraphs [0053]-[0054]). In the second experiment, mouse dendritic Langerhans type cells were generated *in vitro* from mouse bone marrow induced by rat platelets (paragraphs [0055]-[0056]).

In connection with the previously presented amendments to claims 65 and 71, Applicants has specifically identified support for the amendments “in the specification, for

example, at paragraphs 6-13, 25-29, 14-19, 20-24, 30, 31, 50-61 and Figure 1C” on page 5 of the Response filed on September 23, 2008.

B. Step (c) of claims 65 and 71 is adequately described in the Application as filed

No new matter has been introduced by virtue of the previously presented amendments to step (c) of claims 65 and 71. Step (c) of the claimed methods in claims 65 and 71 correlates with the morphological analysis step in the invention described throughout the specification (*e.g.*, paragraphs [0018], [0024] and [0028]). Example 5 provides an example how to perform a morphological analysis to demonstrate the presence of *in vitro* generated dendritic Langerhans type cells by their dendritic processes, and states that “*in vitro* generated human and mouse dendritic Langerhans type cells were analysed under phase contrast microscope” (paragraphs [0048]-[0049]). Consistent with the disclosure in Example 5, two experiments disclosed in the specification further provide that *in vitro* generated dendritic Langerhans type cells were analysed under phase contrast microscope (paragraphs [0054] and [0056]). In particular, growing colonies of cells with typical dendritic morphology were observed in these cells (paragraphs [0054] and [0056]; Fig. 1B; Fig. 3B). Thus, step (c) of claims 65 and 71 is adequately described in the Application as filed.

C. Step (d) of claims 65 and 71 is adequately described in the Application as filed

No new matter has been introduced by virtue of the previously presented amendments to step (d) of claims 65 and 71. Step (d) of the claimed methods in claims 65 and 71 correlates with the flow cytometric analysis step in the invention described throughout the specification (*e.g.*, paragraphs [0019] and [0029]). Example 6 provides an example how to

perform a flow cytometric analysis to demonstrate the presence of *in vitro* generated dendritic Langerhans type cells by immunophenotyping, and states that “[i]mmunophenotyping of *in vitro* generated human dendritic Langerhans type cells was performed by flow cytometry using FACS Calibur (Becton Dickinson, USA) flow cytometer, and the following human cell surface marker specific monoclonal antibodies (mAb): anti-CD3, anti-HLADR, anti-CD19, anti-CD40, anti-CD1a, anti-CD1b, anti[-]CD80, anti-CD83 and anti-CD86 (purchased from Pharmingen, USA)” (paragraphs [0050]-[0051]). Consistent with the disclosure in Example 6, an experiment disclosed in the specification further provides immunophenotyping of cultured cells with these specific monoclonal antibodies (paragraph [0054]; Fig. 2). Based on immunophenotyping results and the morphological analysis results, the presence of *in vitro* generated dendritic Langerhans type cells in the cultured cells was confirmed (paragraph [0054]). Thus, Step (d) of claims 65 and 71 is adequately described in the Application as filed.

D. One of ordinary skill in the art would have known that Applicants were in possession of the claimed invention, including steps (c) and (d), at the time the Application was filed

For the reasons set forth above, contrary to the Examiner’s contention that the limitations introduced into steps (c) and (d) by the previously presented amendments are only found in Example 6 of the specification, description of steps (c) and (d) recited in independent claims 65 and 71, and, therefore, their respective dependent claims 66-70 and 72-75, is adequate and throughout the Application as filed, including but not limited to Example 6. In view of the disclosure in the Application as filed, one of ordinary skill in the art would have known that, at the time the Application was filed, Applicants were in possession of the claimed invention in

claims 65-75, including the morphological analysis step and the flow cytometric analysis step as recited in steps (c) and (d), respectively.

E. The Examiner has improperly suggested that the pending claims recite all limitations in Example 6

The Examiner has apparently erroneously assumed that Example 6 includes paragraph [0054] in contending that Example 6 “only discloses a method of generating human dendritic Langerhans cells from human peripheral blood monocytes,” and “is limited to a method employing only autologous platelets in RPMI-1640 medium with or without 2% fetal calf serum.” As discussed above, Example 6 (paragraph [0050]-[0051]) provides an example of the flow cytometric analysis step in the invention disclosed in the specification and correlates with step (d) in the pending claims while paragraph [0054] describes an experiment according to the invention disclosed in the specification, but is not limited to the flow cytometric analysis step or step (d) in the pending claims. As provided in paragraph [0039], disclosed examples, for example, Example 6 in paragraph [0050]-[0051] and the experiment in paragraph [0054], should not be construed as limitations on the scope of the invention described in the instant application. In view of the supporting disclosure found elsewhere in the specification as discussed above, the Examiner has improperly suggested that the pending claims recite all limitations in Example 6, or, more accurately, paragraph [0054].

If the Examiner were correct, the Examiner should have allowed claim 73, which recites the two limitations identified by the Examiner for Example 6.

In summary, for the forgoing reasons, steps (c) and (d) of claims 65 and 75 are adequately described in the Application as filed, and the previously presented claim amendments


do not constitute new matters. Applicants respectfully request that this rejection of claims 65-75 be withdrawn.

CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Withdrawal of all objections and rejections is also requested.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or refund any overpayments to Deposit Account No. 02-4377.

Respectfully submitted,



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